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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,488	05/25/2001	Anthony E. Bolton	033136-179	4401

7590

08/21/2003

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/866,488

Applicant(s)

BOLTON ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2003, 4/8/2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ :
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-15-2003 has been entered.

Claims 19-30 are pending and examined on merits.

### ***Claim Rejections - 35 USC § 112***

On reconsideration, rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the claims are interpreted as drawn to method of treating the specific diseases listed in the claims.

Claims 19-30 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of treating CHS, does not reasonably provide enablement for any other diseases listed in claim 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant argue that providing enablement for the full scope of the claims is not necessary because FDA monitors efficacy of a pharmaceutical. This argument is

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not convincing because the applicant's disclosure does not meet the enablement provision of 35 U.S.C. 112, first paragraph. The full scope of the instantly claimed method is prevention and treatment of notoriously difficult human diseases and the specification does not provide any in vivo model of any of the diseases except CHS. The art, for example Lui et al (copy provided with Paper No. 6, Human Immunology vol. 60, pages 568-74) recognizes a great deal of unpredictability in the treatment and/or prophylaxis of various diseases listed in the instant claim 19 because the diseases are not very well understood. The current state of art regarding treatment and/or prevention of autoimmune diseases and allograft rejection is still in research and development state. See the first sentence of Liu et al. Applicant further argues the Office's enablement rejection is not supported by scientific literature shown in the four references presented as Exhibit B-E. This argument is not persuasive either because none of the references in Exhibit B-E teaches that the product used in the instantly claimed method can prevent or treat the diseases. The specification is limited to how to make and use apoptotic cells for treating mice with CHS, which is not a model for multiple sclerosis, rheumatoid arthritis, or any other disease listed in the instant claims. The specification does not provide adequate disclosure to enable skilled in the art to make and use the claimed invention without resorting to undue experimentation. The specification fails to teach how to make appropriate apoptotic cells capable of treating or preventing each of specific diseases in instant claim 19. Many of the diseases listed in claim 19 are notoriously difficult to treat. Considering the state of art for prevention and treating the diseases, it is maintained that one skilled in the art would have reasons to

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question the efficacy of the claimed treatment/prevention method in the absence of working examples or other evidence of the claimed method's effectiveness. Applicant is invited to present scientific data showing that the full scope of the claims is enabled. Limiting the scope of the claims to method of treating CHS with the recited active step would also obviate the rejection.

### ***Double Patenting***

The provisional rejection of claim 19 over claim 11 of copending Application No. 09/866,569 is withdrawn because claim 11 does not exist any more and all of the pending claims 16-28 of copending Application No. 09/866,569 are drawn to method of treating congestive heart failure according to Exhibit A and congestive heart failure does not appear to be T-cell-mediated or inflammatory disorders.

### ***Claim Rejections - 35 USC § 112***

Claims 19-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "the patient" in line 5. There is insufficient antecedent basis for this limitation in the claim. All dependent claims are also rejected.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

August 15, 2003

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1600 / 1600